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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,755	10/19/2004	Gregory Pipko	1361-US	4845
24505	7590	12/16/2005	EXAMINER	
DANIEL J SWIRSKY 55 REUVEN ST. BEIT SHEMESH, 99544 ISRAEL			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,755

Applicant(s)

PIPKO ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/14/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on October 14, 2004 with the cancellation of Claims 1-10 without prejudice in view of the restriction requirement. Claims 11-19 are under examination.

Claim Objections

Claim 13 is objected to because of the following informalities: Manuka oil is synonymous with "tea tree oil". Applicant should omit the term "manuka oil" from this claim. Appropriate correction is required.

Claim 19 is objected to because of the following informalities: the following acids are misspelled: "arahinoc" (line 4), "lingocericin" (line 4), "palamtinoleic" (line 5), "lonoleic" (line 6), "undecelenic" (line 6) and "recinoleic" (line 6). "Arahinoc" should be spelled "arachindic ", "lingocericin" should be spelled "lignoceric", "palamtinoleic" should be spelled "palmitinoleic", "lonoleic" should be spelled "linoleic", "undecelenic" should be spelled "undecylenic" and "recinoleic" should be spelled "ricinoleic". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14-16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the emulsifier" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 14-16 recite the limitation "the concentration of the tea tree oil" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claims 14-16 are rendered uncertain by the phrases "the concentration of tea tree oil is between 0.01% to 10%" (lines 1-2, claim 14), "the concentration of tea tree oil is between 0.1 to 1.5%" (lines 1-2, claim 15) and "the concentration of tea tree oil is between 0.1 to 1.5%, wherein the concentration of the product is 0.1% to 1%" (lines 1-2, claim 16) because the amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 16 recites the limitation "the concentration of the product" and "the remainder being water" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the concentration of the additional etheric oils" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the acid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11-13, 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Hyldgaard et al (A).

Applicant claims a fungicidal emulsion comprising tea tree oil and water emulsion wherein the emulsifier is a water solution of a reaction product of high molecular weight organic fatty acid and an alkali or ammonium compound, as Claim 11. Applicant further claims the emulsion according to claim 11, additionally comprising an ethereic oil selected among lavender oil, pine oil, manuka oil, kanuca oil, eucalyptus oil, bergamot oil, clove oil, lemon oil, lemon grass oil, rosemary oil and geranium oil. Applicant further claims the emulsion according to claim 11, wherein the acid is selected among tall oils, naftenic acids, rosin acids and any mixture thereof, saturated fatty acid selected among lauric acid, myristic acid, palmitic acid, stearic acid, arahinoic acid, behenic acid, lingoceric acid or any mixture thereof and unsaturated fatty acids selected among decenoic acid, dodcenoic acid, palmitinoleic acid, oleic acid, lonoleic acid, undecelenic acid, sorbic acid, recinoleic acid or any mixture thereof. Applicant further claims the emulsion of claim 11, wherein the alkali and ammonium compounds are selected

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among sodium, potassium and/or ammonium hydroxides, carbonates, bicarbonates or any mixture thereof.

Hyldgaard teaches an oil-in-water emulsion comprising an oily phase and an aqueous phase (column 39, claim 1). Hyldgaard further teaches the oil-in-water emulsion comprising myristic acid, lauric acid, palmitic acid, stearic acid, arachidic acid, behenic acid, undecylenic acid and lignoceric acid, and mixtures thereof (column 10, lines 33-50 and columns 39 and 40, claims 9 and 10), palmitoleic acid, oleic acid, linoleic acid and mixtures thereof (column 10, lines 33-50 and columns 39 and 40, claims 9 and 10), and sorbic acid (column 18, lines 16-22). Hyldgaard further teaches the oil-in-water emulsion further comprising tall oil fatty acid (column 14, lines 24-25 and 33-36 and column 40, line 17), sodium, potassium and ammonium salts (column 10, lines 21-32), more specifically sodium hydroxide (column 9, lines 43-54) and potassium hydroxide (column 28, lines 27 and 38), tea tree oil (column 18, lines 49-50 and column 19, lines 39-40), eucalyptus extract (column 18, lines 49-50 and column 19, lines 6-7), lavender extract (column 18, lines 49-50 and column 19, line 21), lemon extract (column 18, lines 49-50 and column 19, line 22), pine needle extract (column 18, lines 49-50 and column 19, line 31), rosemary extract (column 18, lines 49-50 and column 19, line 35). Hyldgaard further teaches an oil-in-water emulsion, wherein the oily phase constitutes not more than 50% w/w of the total emulsion in a range of 1-50% w/w, such as about 5-40% w/w and 10-30% w/w (column 13, lines 55-58). Hyldgaard does not specifically teach that the oil-in-water emulsion a fungicide, however, the claimed functional properties are inherent to the preparation taught by Hyldgaard because the ingredients

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taught by Hyldgaard are one in the same as disclosed in the instantly claimed invention of Applicant.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyldgaard (A), in view of Saleh et al. (B) and Lawless (U).

Applicant further claims the emulsion according to claim 11, wherein the concentration of the tea tree oil is between 0.01% up to 10%, between 0.1% to 1.5%. Applicant further claims the emulsion according to claim 14, wherein the concentration of tea tree oil is between 0.1% to 1.5%, wherein the concentration of the product is 0.1% to 1% and the further remainder is water. Applicant further claims the emulsion according to claim, wherein the concentration of the additional etheric oils is between 0.01% to 5%.

The teachings of Hyldgaard are set forth above. Hyldgaard further teaches an oil-in-water emulsion, wherein the oily phase constitutes not more than 50% w/w of the total emulsion in a range of 1-50% w/w, such as about 5-40% w/w and 10-30% w/w (column 13, lines 55-58).

Saleh teaches a multipurpose skin preparation in the form of an oil-in-water emulsion by combining an oil phase and an aqueous phase, wherein the oil phase contains stearic acid (column 6, lines 19-20 and lines 35-42), lavender oil (column 10, lines 16-43) and other adjunct ingredients, such as tea tree oil, which are anti-bacterial agents and anti-fungal agents (column 7, lines 42-47 and lines 56-64). Saleh further teaches that tea tree oil is believed to aid as an antibacterial and antiseptic (column 7, lines 42-47 and lines 56-64). Saleh further teaches that tea tree oil is present in a range

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from about 0.001% to about 4% by weight of the total skin preparation and preferably in the amount of about 0.02% by weight (column 7, lines 56-64).

The individual teachings of Hyldgaard and Saleh are set forth above. Saleh does not expressly teach an alkali or ammonium compound nor does Hyldgaard nor Saleh expressly teach a concentration of tea tree oil between 0.01 and 10% nor does Hyldgaard nor Saleh expressly teach a concentration of tea tree oil between 0.1 and 1.5% nor does Hyldgaard nor Saleh expressly teach a concentration of tea tree oil between 0.1 and 1.5%, wherein the concentration of the product is 0.1% to 1% and further wherein the remainder being water.

However, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to modify the oil-in-water emulsions taught by either Hyldgaard or Saleh to provide the instantly claimed invention because at the time the invention was made, the bioactive effects of tea tree oil, particularly as an fungicidal agent (See Lawless, page 169), were well known in the art, as clearly taught by Hyldgaard and Saleh.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of tea tree oil and the concentration of the product and the percentage amounts of the ingredients thereof to provide an emulsion comprising tea tree oil and water emulsion wherein the emulsifier is a water solution of a reaction product of high molecular weight organic fatty acid and an

alkali or ammonium compound, as taught by Hyldgaard and Saleh. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of solvent used to perform an extraction and determining an appropriate type of solvent to use in an extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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As the reference indicates that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark
AU 1655

Amy L. Clark
December 5, 2005



CHRISTOPHER R. TATE
PRIMARY EXAMINER